REMARKS

This amendment adds, changes and/or deletes claims in this application. A detailed listing is provided, with appropriate status identifiers, for all claims that are or were in the application, irrespective of whether any given claim remains under examination. More specifically, claims 1 and 11 are revised to remove a duplicate entry of "W-M61." Claim 8 is amended to correct the spelling of "hepatocellular." Also, a missing period has been added to claim 14.

In response to a restriction requirement, claims 8-14 have been withdrawn. Applicants reserve the right to file one or more divisional applications to cover the subject matter of the non-elected claims.

Upon entry of this response, claims 1-7 will be pending. Applicants respectfully request reconsideration of those claims and the present application, in view of the foregoing amendments and these remarks.

I. OBJECTIONS TO SPECIFICATION

The examiner objects to the specification for the use of the trademark ProteinChip®. Applicants believe the above-entered amendments obviate the objection. In addition, applicants note that the mark is theirs and that the specification substantively describes the chips on page 25. Applicants believe, therefore, that the rejection should be withdrawn.

II. RESTRICTION REQUIREMENT

Beyond the formal restriction requirement, the examiner attempts to further divide independent claims 1, 8 and 11 by requiring applicants to further elect a single protein for examination. The examiner's so-called "Protein Election Requirement" is legally flawed, however, and should be withdrawn.

Under the Patent Statute, an applicant enjoys a right, pursuant to §112, to claim his invention with whatever qualifications that he regards as necessary to circumscribe that invention. *See In re Weber*, 580 F.2d 455, 458 (CCPA 1978) (copy appended). Furthermore, the Federal Circuit's predecessor recognized that "an applicant has a right to have each claim examined on the merits." *Id.* Yet, the examiner here seeks to deny applicants that right by arbitrarily parsing the independent claims into uses of individual proteins.

While "[35 U.S.C.] §121 provides the Commissioner with the authority to promulgate rules designed to Restrict an Application to one of several claimed inventions when those inventions are found to be 'independent and distinct' . . . [i]t does not [ ] provide a basis for an examiner acting under the authority of the Commissioner to Reject a particular Claim on that same basis." *Id.* Accordingly, the Federal Circuit's predecessor has held that "[i]f [ ] a single claim is required to be divided up and presented in several applications, that claim would never be considered on its merits."

Thus, the tack now sought by the examiner has been specifically prohibited. The so-called "Protein Election Requirement", therefore, should be withdrawn.

III. REJECTIONS UNDER 35 U.S.C. § 112

The examiner rejects claims 1-7 for an alleged lack of written description. Applicants respectfully traverse the rejection.

Proceeding under his faulty restriction requirement, the examiner focuses on a single protein marker, I-M38. The examiner simply asserts that the specification lacks written description because "[t]he specification does not teach any structural limitations of I-M38." Office Action, pg. 5, ¶ 2. The examiner's assertion is legally flawed, however.

Contrary to the examiner's assertion, §112 does not require the specification to provide the structure of I-M38. All that is required to satisfy the "written description" requirement of §112, according to the Federal Circuit, is that the application convey with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the claimed invention. *See Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991).

In the instant case, the claims are directed to methods of qualifying hepatocellular carcinoma status in a subject, comprising analyzing a biological sample from the subject for a diagnostic level of one or more specific protein markers. The specification explains how to analyze a biological sample for each of the noted biomarkers. *See, e.g.* Application, pg. 10-14, Examples 1-3, and Figures 1 & 2. For instance, a serum sample is analyzed for a level of protein marker I-M38 by exposing serum fraction 6 to an IMAC3 ProteinChip® Array and determining the concentration of a protein with a molecular weight of approximately 8,942 daltons. *Id.* Furthermore, Examples 1-3 show that applicants used the claimed biomarkers, including I-M38, to evaluate 40 patients with hepatocellular carcinoma (HCC) and 21 patients with chronic liver

disease (CLD). Using the claimed biomarkers, applicants distinguished HCC patients from CLD patients with a high degree of success, *i.e.,* greater than 85%. For example, see application at pages 15-19.

Accordingly, one of skill in the art would readily recognize that, as of the filing date, applicants were in possession of the claimed methods. The rejection, therefore, should be withdrawn.

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Applicants submit that the present application is in condition for allowance, and they request an early indication to this effect. Examiner Archie is invited to contact the undersigned directly, should she feel that any issue warrants further consideration.

The Commissioner is hereby authorized to charge any additional fees, which may be required under 37 CFR §§ 1.16-1.17, and to credit any overpayment to Deposit Account No. 19-0741. Should no proper payment accompany this response, then the Commissioner is authorized to charge the unpaid amount to the same deposit account. If any extension is needed for timely acceptance of submitted papers, applicants hereby petition for such extension under 37 CFR §1.136 and authorize payment of the relevant fee(s) from the deposit account.

Respectfully submitted,

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Date 23 May 2008

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